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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,106

02/16/2007

Rudolf Moser

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6288

4743

7590

06/25/2009

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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

06/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,106	Applicant(s) MOSER ET AL.	
	Examiner Erich A. Leeser	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 130-168 is/are pending in the application.
- 4a) Of the above claim(s) 130-160 and 168 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 161-167 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-23-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second action on the merits and is in response to Applicant's submission dated April 2, 2009, in which Applicant elected the invention of Group IV, drawn to three-step processes useful for forming enantiomerically-enriched tetrahydrobiopterin (BH₄) or a salt thereof from neopterin, classified in class 544, subclass 251. Claims 161-167 are under examination and claims 130-168 and 168 are withdrawn from consideration.

Information Disclosure Statement

The references contained in the IDS dated March 23, 2007, are made of record.

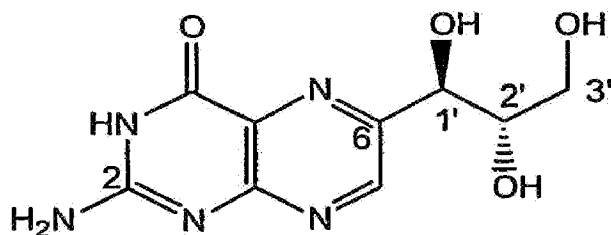
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 161-167 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The schematic representation of the elected process can be seen in Fig 4. Step (b) in claim 161 recites that: "converting primary hydroxyl group of neopterin to a thioether". The structure of neopterin (as disclosed in the specification at page 6) is depicted below:

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Step (b) is directed to the $\text{-CH}_2\text{-OH}$ at the 3' position above to a $\text{-CH}_2\text{-S-R}$ (i.e., the thioether).

This has to be done by first protecting the -OH groups at the 1' and 2' positions and then *selectively* converting the primary hydroxyl (shown at 3' position in the structure above) and can not be done without prior protection of the remaining hydroxyls. Thus, protecting the two hydroxyls is an "essential method step" that has been omitted from the claims. None of the claims provide how the selective conversion of the primary hydroxyl is done. Correction is required.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 161-167 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Steps critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Step (b) in claim 161 recites that: "converting primary hydroxyl group of neopterin to a thioether". See the structure of neopterin, *supra*. Step (b) is directed to the $\text{-CH}_2\text{-OH}$ at the 3' position above to a $\text{-CH}_2\text{-S-R}$ (i.e., the thioether). This has to be done by first protecting the -OH groups at the 1' and 2' positions and then *selectively* converting the primary hydroxyl (shown at 3' position in the structure above) and can not be done without prior

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protection of the remaining hydroxyls. Thus, protecting the two hydroxyls is an "critical or essential" to practicing the claimed invention. However, none of the claims provide how the selective conversion of the primary hydroxyl is done. As such, the invention is not sufficiently enabled to allow one skilled in the art to make or use the invention as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

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